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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,084	09/06/2000	Barry N. Kreiswirth	19124.0002	8869

23517 7590 04/05/2002

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EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/05/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,084	KREISWIRTH ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner. (See PTO 948)

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of species (a) claims 1, 5-9, 13-20 and 28-30 in Paper No. 7, filed 19 December 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Although applicant did not traverse the restriction requirement, upon further review of the claims, the species election set forth in Paper No. 5, mailed 23 October 2001, is hereby vacated. All claims have been fully examined on the merits.

Drawings Notice

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached to the back of the PTO-948, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The

factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claim 1, 32 and 33 fail to define that which is considered "real-time" for performing "real-time infection control" (claim 1, line 1). The specification on page 8 relies upon a known characterized region that is also a fast mutating region in order to accomplish infection control in 'real-time'. However, only identification of a couple characterized regions such as the protein A gene (spa) or coagulase (*coa*) gene regions of the *Staphylococcus aureus* are disclosed. Nowhere in the claims or the specification is there a clear and direct explanation as to how microorganisms other than the *Staphylococcus aureus* are to be analyzed for phylogenetic relatedness for real-time infection control. In addition, nowhere in the claims or the specification is there a clear and direct explanation as to how pathogenic microorganisms without fast mutating regions are to be analyzed for phylogenetic relatedness for real-time infection control. The specification on page 18 discloses a possible sequence analysis of a microorganism from a dialysis machine, yet does not provide any guidance as to how. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. The specification as originally filed requires undue experimentation by one of skill in the art since methods of infection control analysis for every microorganism are not currently known. Given the lack of working examples in the specification, and the unpredictability of real-time infection control in the context of any microorganism, the specification, as filed is not enabling for the method of analyzing any sample microorganism as claimed. As such, claims drawn to the microorganism sample are not enabled.

Claim 10 fails to clarify what the infection risk factor determination is based upon. Nowhere in the specification is the generation of the measure of infection risk factor defined for one of ordinary skill in the art to know whether to ignore the data from the sample and determine the infection risk factor solely upon the patient's medical history. While working examples are

not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of determining infection risk factors, the specification, as filed is not enabling for the method of using infection risk factors in the method of real-time infection control as claimed. As such, claim 11 is also not enabled due to dependency from claim 10.

The instant application fails to provide guidance to one of ordinary skill in the art for generating the following "costs" as recited in claims 15-18: relative cost, absolute cost, repeat motif cost, point mutation cost, and total cost (which is based upon the summation of the repeat cost and point mutation cost). For example, the specification on page 30 (lines 10-13) describes what is indicative of low or high relative costs but does not provide or suggest what these "costs" are generated, calculated, measured, or determined from. Page 32 of the specification discloses that the relative cost is "a measure of the similarity of the repeat motifs of the two sequences being compared" (lines 3-4). The specification discloses the relative cost is a measure of phylogenetic relatedness yet does not teach how this measurement is accomplished in a positive active fashion. The prior art of record does not teach the determination of these "costs". In terms of the total cost summation as indicated on page 32 of the specification (lines 12-13), if the repeat motif cost and the point mutation costs are not enabled then a summation of the two is not enabled either. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of generating the listed "costs", the specification, as filed is not enabling for the method of using the following "costs" in the method of determining phylogenetic relatedness or distance as claimed: relative cost, absolute cost, repeat motif cost, point mutation cost, and total cost. As such, claims 19-20 are also indefinite due to dependency from claims 15-18.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 32 and 33 are vague and indefinite due to the lack of clarity in the language "real-time". It is unclear as to length of time required for real-time infection control. The parameters of that which real-time must fall within to be considered real-time is not defined in any manner. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1 is vague and indefinite due to the preamble reciting a method over a computer network, but the body of the claim has no requirement of a computer network. Besides the storage of data in a database no computer hardware is required of the claim. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1 is vague and indefinite due to the term "historical" lacking a clear and definite definition. It is unclear if the applicant means for anything up to the present is considered to be historical or if this is with respect to a known (but unidentified) database. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claims 1 and 28 fail to clarify the database being utilized. It is unclear what the difference is between the database of claim 1 and the centralized database of claim 28. It is also is vague and indefinite whether either of the claimed databases retains information of historical sequence data, historical samples, or historical sample sequence. If sequence data was intended, then the metes and bounds of sequence data are unclear as to whether full sequences, partial sequences, or both are stored. If the historical sample was intended, then it is unclear if the database stores an actual biological sample (and if so how) or information about a sample. As such, claims 2-27 and 29-31 are also indefinite due to their dependency from claims 1 and 28.

Claim 1, 32 and 33 are vague and indefinite due to the lack of clarity in the microorganism sample. It appears to state that a sample is taken from the microorganism itself versus a patient or object as disclosed in the specification. In addition, there is no requirement that the sample must be one containing an infectious agent. Samples can carry microorganisms that are naturally within the body of a patient and are not infectious agents or within a stage of infection (i.e. E.coli). As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1 is vague and indefinite due to the lack of clarity in the step of providing infection control information to the remote facility of lines 9-10. The process of determining phylogenetic relatedness appears to be occurring within the remote facility already. Thus making it unclear as to why information determined from phylogenetic relatedness would need to be provided to the facility. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1, 32 and 33 fail to clarify the correlation between the phylogenetic relatedness determination and the infection control information when the sample being analyzed is not limited to only infectious microorganisms. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claims 1, 32 and 33 are vague and indefinite due to the lack of clarity in the claim language "infection control information" (claim 1, line 9). It is unclear as to what the applicant regards as information necessary for infection control. The following are examples of possible interpretations that are not clarified within the specification: antibiotic resistance or susceptibility; selection of disinfectants to be used within the health care facility; spread or prevalence in geographic areas; and presence or absence of infectious agents within the sample. It is also unclear how this information differs from that information on drug resistance and treatment determined in claim 26. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1 is vague and indefinite due to the lack of clarity in the location of the sample analysis or phylogenetic relatedness determination. It is unclear in where the phylogenetic relatedness determination is performed, and from where the infection control information based upon the phylogenetic relatedness is being provided. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 1 is vague and indefinite due to the lack of clarity in the claim language being interchanged "phylogenetic relatedness" and "phylogenetic distance". If the two terms "relatedness" and "distance" are not the same, then the bodies of claim 16 and 17 do not accomplish the method of the preamble. As such, claims 2-31 are also indefinite due to their dependency from claim 1.

Claim 3 is vague and indefinite due to the lack of clarity of the database location being in an infection control facility. Claim 3 depends from claim 1 which lacks a step of sample

submission or sample transmission over a network to an infection control facility. In addition, claim 1 infers that the microorganism sample analysis and storage occurs at the remote facility at which the sample is obtained (line 3 of claim 1).

Claim 4 is vague and indefinite due to the lack of clarity in the database location in the remote facility. If the database is at the remote facility, then it is unclear as to why claim 1 from which claim 4 depends, requires a step to provide the information determined at the facility in order to "provide" information to the facility in which it was determined. As such, claims 6-8 are also indefinite due to their dependency from claim 4.

Claim 5 is vague and indefinite due to the lack of clarity in the language "has been identified" lines 1-2. The region identification step is lacking from claim 5 and claim 1 from which claim 5 depends.

The term "suitably fast" in claim 5 is a relative term that renders the claim indefinite. The term "suitably fast" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 6 is vague and indefinite due to the improper dependence from claim 4. It is unclear how the sequenced region of claim 6 further limits the database location limitation of claim 4. As such, claims 7 and 8 are also indefinite due to their dependency from claim 6.

Claim 7 is vague and indefinite due to the improper dependence from claim 6. It is unclear how the specified microorganism of claim 7 further limits the repeat region limitation of claim 6. As such, claim 8 is also indefinite due to its dependency from claim 7.

Claim 8 is vague and indefinite due to the improper dependence from claim 7. It is unclear how obtaining a sample from a patient in claim 8 further limits the microorganism and region specification of claim 7.

Claims 8, 11, 23, 26, 27, and 32 recite the limitation "the health care facility". There is insufficient antecedent basis for this limitation in the claims. As such, claim 24 is also indefinite due to its dependency from claim 23.

Claim 10 is vague and indefinite due to the lack of clarity in the infection risk factor determination. Nowhere in the claim is it a requirement that the microorganism sample be an infectious isolate. If an infectious isolate is intended then, the patient from whom the sample is

taken must already be infected. If already infected, it is unclear why a measure of the patient's risk of "acquiring an infection" (line 5) or infection risk factor is determined. As such, claim 11 is also indefinite due to their dependency from claim 10.

Claim 11 is vague and indefinite due to the lack of clarity in the language "sensitive patient information" line 4. The metes and bounds as to what defines sensitive information are not clear.

Claims 12, 22, 23, 25 and 26 recite the limitation "the centralized database". There is insufficient antecedent basis for this limitation in the claims. As such, claim 24 is also indefinite due to its dependency from claim 23.

Claim 12 is vague and indefinite due to the lack of clarity in the location of the centralized database in line 3. It is unclear as to where the database is if not at the remote facility. Claim 1 from which claim 12 depends, does not recite any other facility than the remote facility.

Claim 15 is indefinite for failing to recite a final process step that agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. For example, claim 15 is drawn to the step of determining the phylogenetic relatedness, yet the claim recites final steps only calculate particular costs. The claims do not set forth a step of correlating these calculations to the determination of phylogenetic relatedness. As such, claims 17-20 are also indefinite due to its dependency from claim 16.

Claims 16 and 17 recite the limitation "the similarity" in lines 6 and 9 of claim 16, and line 2 of claim 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 is vague and indefinite due to the lack of clarity in the language "comparing to historical samples" in line 4. It is unclear as to what is being compared. If the microorganism sample is that which is intended to be compared to the historical sample, then it is unclear as to what between the two samples is under comparison.

Claim 21 recites the limitation "the same region" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 fails to define what region is under consideration. The term "region" itself is vague and indefinite. It is unclear whether sequence region or geographical region is intended.

If geographical region is intended then it is unclear as to whether the patient's geographical region, remote facility geographic region, or microorganism's origin region is intended.

Claims 22 and 24-27 are vague and indefinite due to the lack in clarity in the step of "transmitting". Due to the lack of computer hardware or computer network requirements in claim 1 from which claim 22 depends, it is unclear as to how the transmitting step can occur.

Claims 22 and 24 are vague and indefinite due to the lack of clarity in the physical location of the patient. It is unclear if the "sensing" step occurs before or after the determination of the patient's physical location. It is unclear if the two claims are referring to the same location. The specification discloses the tracking of the patient only within a health care facility. Thus which physical location is under consideration is unclear; both claims "transmi[t] the physical location of the patient".

Claim 24 recites the limitation "the centralized server" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 fails to clarify for whom or what the drug resistance or treatment information is being determined for. For example, it is unclear whether the treatment information is based upon the microorganism or the treatment information is a regimen for the patient from which the sample was taken.

Claim 27 is vague and indefinite due to the lack of clarity in the claim language "potential outbreak problem" line 2. The metes and bounds of potential is not clearly defined. All health care facilities have potential outbreak problems, thus it is unclear what applicant claims as the level of risk that warrants a warning.

Claim 28 is vague and indefinite due to the lack of clarity in the difference between the centralized database of line 4 and the database of claim 1 line 6.

Claim 30 fails to clarify which sample is indicated by "the sample" in lines 2 and 4. It is vague and indefinite whether it is the microorganism sample or the historical sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, 12, 21, 25-27, 32 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Shopsin et al (*J. Clin. Microbiol.*, 1999).

Shopsin et al demonstrates a method for determining genetic relatedness rapidly in hospital investigations by the subtyping of *Staphylococcus aureus* strains for "simplify[ing] the sharing of information between laboratories and facilitat[ing] the creation of a large-scale database for the study of global as well as local epidemiology" (p. 3562, 1st column, last paragraph), as recited in claims 1-5, 9, 12 and 21. Sequence analysis was performed upon the protein A gene, repeat region, utilizing a set of primers for region identification and amplification (p. 3557, 1st column, last two paragraphs) as recited in claims 6, 7, 13 and 14. The reference also demonstrates the uses of the method for outbreak investigations by "aid[ing] the identification of strains that have special virulence properties or drug resistance" (p. 3562, 2nd column, 3rd paragraph), thus motivating claims 25-27. To validate lineages as recited in claims 28 and 29, Shopsin et al "will assess whether *spa* repeat types (either alone or in combination with other alleles) can be accurately compared" (p. 3562, 2nd column, 3rd paragraph). Shopsin et al demonstrates the computer implementation of the method by use on an Internet Web site, analysis software packages, central and local databases for "rapid exchange of strain typing information without having to transfer bacterial strains" (p. 3562, 1st column, bridging paragraph) thus anticipating claims 32 and 33.

Shopsin et al is appropriately applied to the claims due to the difference in the listing of participating authors of the reference and the inventors of the instant application.

Claims 1-4, 9, 12, 21, 25-27, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Levitt (*Emerg. Infect. Dis.*, 1998).

Levitt demonstrates the use of the European Union's Enter-net system for the surveillance of infectious diseases. The reference states that the Enter-net participants carry out "procedures for serotyping, phage typing, and toxin typing" (p. 502, 2nd column, lines 4-10) in order to report disease cases through the Internet to the international database of Enter-net. In

addition, Levitt demonstrates that the Center for Disease Control initiated in 1996 PulseNet, "a national molecular subtyping network for tracking *E.coli*" (p. 502, 2nd column, lines 29-33) and is being expanded to include other foodborne pathogens. The reference states that the PulseNet electronic database, accessible by participating laboratories, "will include DNA patterns of foodborne pathogenic bacteria and epidemiologic information associated with these isolates" (p. 506, 1st column, lines 1-5). In addition, Enter-net demonstrates an upgrade of the network to include "antimicrobial resistance testing" (p. 503, column 2, 1st paragraph). Thus this reference demonstrates the use of a centralized database, remote facility, infection control facility, computer network, Internet, for controlling infections globally and regionally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 12-14, 21, 25-29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitt, in view of Frenay et al (*Eur. J. Clin. Microbiol. Infect. Dis.*, 1996) and Hoe et al (*Emerg. Infect. Dis.*, 1999).

Levitt is applied as described above. Levitt does not demonstrate specified regions of sequencing or method of sequence analysis as recited in claims 5-7, 13, 14, 28 and 29.

Frenay et al teaches a method of epidemiological typing of a repeat region, protein A gene, of the microorganism *Staphylococcus aureus* (abstract). The method includes the region identification by primers and amplification prior to sequencing (p. 61, 1st column, 3rd paragraph) as recited in claims 13 and 14. Mutation rates are also taken in consideration on page 63 (2nd column, 3rd paragraph). Frenay et al clearly suggests the use of the specified region as an "important tool in unraveling the spread of MRSA strains within and between hospitals" (abstract).

Hoe et al teaches the sequence analysis of more than one region for "inferring epidemiologic relationships in potential outbreaks" (p. 257, 1st column, 1st paragraph) as recited in claims 28-31.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to perform the computer-implemented network method of Levitt involving sample analysis, infection control facilities, remote facilities, databases, international and national network connections; and to modify the infection control sample analysis using sequence analysis of the protein A gene, of the microorganism *Staphylococcus aureus* as per the teachings of Frenay et al and the multiple region analysis as per the teachings of Hoe et al. Thus, one of ordinary skill in the art would have been motivated to have performed the claimed invention with a reasonable expectation of success.

Claims 1-14, 21, 22-29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitt, Frenay et al, Hoe et al, in further view of O'Brien et al (*CHEST*, 1997) and Carroll et al (U.S. Patent 5,396,227; filed May 5, 1993).

Levitt, Frenay et al and Hoe et al are applied as described above. Frenay et al, Hoe et al and Levitt, do not demonstrate patient medical history exchange as recited in claims 10 and 11, and patient tracking as recited in claims 22-24.

O'Brien et al teaches a method of comparing "genetic relatedness among *Mycobacterium tuberculosis* isolates recovered from patients with active disease" (p. 387, 2nd column). Due to the tracking the patients medical records by Bellevue Hospital and the Department of Health in New York City, patients found not adhering to therapy were quarantined. This displays tracking a patient's physical location as well as the sharing of patient medical information as recited in

claims 10, 11 and 22. Sample analysis of the infected individuals occurred prior confinement in the health care facility as recited in claim 8. The "clinical and demographic features of these patients" (p. 390, 2nd column, 1st paragraph) were reviewed for population risk factors in addition to determining "ongoing transmission of tuberculosis" (p. 388, 1st column, 3rd paragraph) as recited in claim 10.

Carroll et al demonstrates that the physical sensing of an individual is well known in the art. The reference teaches an electronic monitoring system, portable and centralized, that monitors the location of an individual by a transmitter tag (abstract) thus motivating claims 23 and 24.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to perform the computer-implemented network method of Levitt in view of Frenay et al and Hoe et al, involving sequencing specified regions in sample analysis; and to further modify the patient history and tracking from which the sample was obtained as per the teachings of O'Brien et al. In addition, one of ordinary skill in the art at the time of the invention was made to perform the patient method of O'Brien and further modify the physical tracking as per the teachings of Carroll et al. Thus, one of ordinary skill in the art would have been motivated to have performed the claimed invention with a reasonable expectation of success.

Claims 1-14, 21, 22-29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shopsin et al (*J. Clin. Microbiol.*, 1999) in view of O'Brien et al (*CHEST*, 1997) and Carroll et al (U.S. Patent 5,396,227; filed May 5, 1993).

Shopsin et al is applied as described in the 35 U.S.C. 102(a) rejection above. Shopsin et al does not teach the patient medical history exchange as recited in claims 10 and 11, and patient tracking as recited in claims 22-24.

O'Brien et al is applied to claims 10, 11 and 22 as described in detail above; and Carroll et al is applied to claims 23 and 24 as described in detail above.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to perform the genetic relatedness determination method of Shopsin et al and further modify infection control by the patient history and tracking from which the sample

was obtained as per the teachings of O'Brien et al. In addition, one of ordinary skill in the art at the time of the invention was made to perform the patient method of O'Brien and further modify the physical tracking as per the teachings of Carroll et al. Thus, one of ordinary skill in the art would have been motivated to have performed the claimed invention with a reasonable expectation of success.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 4, 2002

Monika B. Sheinberg
Art Unit 1631

MBS

Marianne P. Allen

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